

Brussels, 27 August 2018

Object: Plasticisers in the SIN List

Dear Ms. Andersson,

I am writing on behalf of the members of European Plasticisers, a Cefic Sector Group representing the European producers of plasticisers. I would like to bring to your attention some inaccuracies with regard to certain major plasticisers, which are included on the ChemSec SIN list, as follows:

- **DINP (CAS numbers 68515-48-0 and 28553-12-0; EC numbers 271-090-9 and 249-079-5)**
DINP is NOT a “substance of equivalent level of concern” under article 57(f) of REACH as is stated on the ChemSec website re: [“Official classification missing – Article 57f substance”](#). Neither is it correct to state “Official classification missing” since DINP was previously the subject of an EU Risk Assessment in 2006 which at that time included the classification assessment with the conclusion of “No classification required” for any health or environmental hazard.

More recently (March 2018) all the relevant data on DINP have been the subject of a further in-depth assessment by the ECHA RAC regarding a CLP proposal on reproductive toxicity. As stated in the Annex to the media release by ECHA on March 16, 2018: “Contrary to the proposal from Denmark, RAC concluded the data on DINP do not warrant classification for reproductive toxicity”. This conclusion, adopted by consensus, was based on the lack of adverse reproductive effects in animal and epidemiology studies (two fertility studies, thirteen developmental studies and fifteen repeat dose toxicity studies, 8 epidemiology studies). The full RAC opinion has been published in June 2018 with the conclusion that: [“Overall, RAC concluded that no classification for DINP for either effects on sexual function and fertility, or for developmental toxicity is warranted”](#).

Further, we would note that the Danish Environment Ministry (including the Danish EPA) have accepted the RAC decision and have stated [“The DEPA has taken note of RAC’s decision and will not pursue the matter further”](#).

In addition, we also note statements from the German Federal Risk Institute (BfR - Dr. Agnes Schulte, RAC member) that “plasticisers cannot be lumped together, and for [the most important phthalate, REACH gave the ‘all-clear signal’](#)”.

In view of the lack of adverse effects for the endpoint relevant to LMW phthalates (reproductive effects) the data do not then support referring to DINP as a “suspect endocrine disruptor” as is done on the ChemSec website, since adverse effects are a key element for the WHO definition of endocrine disruptors (together with a mode of action and evidence of a plausible link with the adverse effect).

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European Plasticisers therefore respectfully requests ChemSec to correct the SIN list by removing DINP.

- **DIDP (CAS number 68515-49-1 and 26761-40-0; EC numbers 271-091-4 and 247-977-1)**

It is not accurate to state "[Official classification missing](#)" for DIDP since this substance was the subject of an extensive EU Risk Assessment under the EU Existing Substances Regulation published in 2006 (which included classification assessment at that time), with the conclusion that classification is not warranted for any health or environmental hazard.

The statement on DIDP on the ChemSec website that "This substance has endocrine disrupting properties. Exposure to diisodecyl phthalate in vivo has led to disturbed reproduction and development in rodents, daphnia and fish. There is in vitro evidence of thyroidogenic activity and in vivo and in vitro evidence of estrogenic action" is not supported by the scientific data and the regulatory assessments which have been carried out. DIDP has been the subject of a further evaluation by ECHA (2013) on the new data available since the EU Risk Assessment with the conclusion that DIDP does not induce any substantial anti-androgenic activity in available studies. The ECHA re-evaluation for both DINP and DIDP included over 440 references to scientific studies and reviews including the five studies which serve as the basis for the ChemSec listing. Lack of antiandrogenic activity of DIDP is further confirmed by Furr et al. (2014), *Toxicol Sci*(2), 403–424: No indication for anti-androgenic activity was found for DIDP. The absence of adverse reproductive effects and other adverse effects precludes endocrine disruption since the definition requires adverse effects, a mode of action and a link between the two. Therefore, it is not appropriate to refer to DIDP as an endocrine disruptor.

Extensive studies on daphnia and fish have also shown a lack of adverse effects and these studies were available as part of the EU Risk Assessment with the conclusion that classification for adverse environmental effects is not warranted. The extensive regulatory reviews on DIDP have concluded that there are no adverse effects.

European Plasticisers would therefore respectfully request that ChemSec updates the SIN list by removing DIDP.

- **DEP (CAS 84-66-2, EC number 201-550-6)**

The following statements on the ChemSec website is not supported by the scientific data: "Diethyl phthalate (DEP) is an endocrine disruptor with thyroid and estrogenic activity, affecting several body functions and target organs including reproduction, liver and metabolism" and "[Official classification missing – Article 57f substance](#)". Reproductive and other relevant studies have been conducted on DEP with the conclusion that classification is not required – [see the ECHA website for details](#).

We also note that in 2014 Germany completed a CoRAP evaluation on DEP for suspect CMR and suspect endocrine disrupting properties and concluded: "[There is no need for regulatory follow-up action](#)".

European Plasticisers would therefore respectfully request that ChemSec updates the SIN list by removing DEP.

Structure activity and phthalates

In the discussions on structure activity of phthalates and reproductive effects in the context of a proposal for classification of DIOP, RAC also agreed that the adverse reproductive effects seen in animal studies are associated with C3-C6 carbon backbones in the alkyl side chains of the diester, and hence not with C7 and above, nor C1 (DMP) or C2 (DEP) alkyl side chains. These RAC conclusions on structure activity provide further confirmation on the lack of scientific justification for including DEP, DINP and DIDP in the SIN list.

While European Plasticisers fully shares stakeholder objectives to ensure the safe and sustainable use of chemicals with regard to the view on “removing hazardous chemicals from the world”, European Plasticisers would note that many naturally occurring chemicals like essential trace elements or vitamins are highly toxic and hazardous, for example vitamin A (essential for vision), which causes severe adverse effects in animal reproductive studies at increased dose levels.

Since all substances can be toxic at some dose level, we believe it is essential that risk assessment is taken into account in order to ensure a sustainable approach to chemicals management. With a hazard only approach many substances bringing essential benefits to society will be lost without any benefit to health or the environment.

European Plasticisers would also note that the livelihoods of many thousands of businesses and their employees depend upon the production and use of plasticisers in flexible vinyl applications, and that the safe and sustainable use of such substances is a top priority for these companies. In this context, we would refer to the [VinylPlus Sustainability Initiative](#). The essential benefits which the products bring to society also include health, environmental and sustainability benefits in healthcare, construction, transportation and telecommunications.

European Plasticisers would much appreciate your prompt action on the above updating of the SIN List as this is creating unjustified confusion in the global market place, as well as undermining the scientific credibility of ChemSec.

Thank you in advance for your consideration of these points. We are open to further discuss the above information as appropriate.

Yours sincerely

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Manager of European Plasticisers